

Blumberg & Wolk, LLC

158 Delaware Street

P.O. Box 68

Woodbury, NJ 08096

(856) 848-7472

Counsel for Defendants Premier Orthopaedic and Sports Medicine Associates of Southern New Jersey, LLC, trading as Premier Orthopaedic Associates, Premier Orthopaedic Associates Surgical Center, LLC, Kimberly Yvette Smith, M.D., a/k/a Kimberly Yvette Smith-Martin, M.D., Thomas Dwyer, M.D., Rhaul Shah, M.D., John Catalano, M.D., Richard C. DiVerniero, M.D., and Richard Strauss, M.D.

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

IN RE: NEW ENGLAND COMPOUNDING
PHARMACY, INC. PRODUCTS
LIABILITY
LITIGATION

THIS DOCUMENT RELATES TO:

ALL CASES

MDL No. 2419

Docket No. 1:13-md-2419 (RWZ)

**PREMIER ORTHOPAEDIC ASSOCIATES, ET AL'S OPPOSITION TO THE EMORY
CLINIC'S MOTION TO QUASH SUBPOENA FOR DEPOSITION BY WRITTEN
QUESTION**

Defendants Premier Orthopaedic and Sports Medicine Associates of Southern New Jersey, LLC, trading as Premier Orthopaedic Associates, Premier Orthopaedic Associates Surgical Center, LLC, Kimberly Yvette Smith, M.D., a/k/a Kimberly Yvette Smith-Martin, M.D., Thomas Dwyer, M.D., Rhaul Shah, M.D., John Catalano, M.D., Richard C. DiVerniero, M.D., and Richard Strauss, M.D. (collectively, "Premier Defendants" or "Premier") hereby oppose The Emory Clinic's

(Hereafter “TEC”) Motion to Quash the Subpoena for Deposition by Written Question (Docket Numbers (“Dkt. Nos.”) 2777, 2778, 2779, 2780).

BACKGROUND

The New England Compounding Center (“NECC”) had thousands of customers across the Nation. Prior to the 2012 fungal meningitis outbreak NECC was the source of contaminated MPA, which culminated in this litigation. According to the “(NECC) Customer List since 5/21/2012” published on the FDA’s website, The Emory Clinic Ambulatory Surgical Center (Hereafter “TEC”) placed approximately twenty-one (21) orders with NECC between May 21, 2012 and August 24, 2012. TEC is a non-party.

The orders TEC placed with NECC appear to range in quantity from twenty-five (25) to one-hundred and sixty (160) units per order. Given the dosage formats listed for these medications, most of which appear as “ML” (milliliter), “U/ML” (unit per milliliter), or “MG/ML” (milligram per milliliter), the Premier Defendants infer that all medications were ordered in liquid form; several are further specified with a delivery method of “dropper,” “vial,” or “injectable.”(<http://www.fda.gov/downloads/Drugs/DrugSafety/FungalMeningitis/UCM325466.pdf>, pg. 309 of 345).

The medications ordered by TEC included: Phenylephrine, Tropicamide preservative free, “Cyclo”, Ketorolac preservative free, Hyaluronidase Preservative Free, Phenylephrine-Atropine Ophthalmic Solution, Triamcinolone Acetonide Preservative Free, and Sodium Chloride Injectable. *Id.* Some of the orders appear to indicate possible combinations of the above-listed drugs or multiple disparate drugs ordered at once; the notation is unclear.

Of these, TEC placed an order on July 25, 2012 for “Triamcinolone Acetonide, 40 MG/ML preservative free, 2 mL.” Triamcinolone Acetonide “injectable suspension” is also known as the

brand-name Kenalog – described by the FDA as a “synthetic glucocorticoid corticosteroid.” (https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/014901s038lbl.pdf). NECC marketed vials of “Preservative-Free Kenalog” to customers, with flyers that can be found in the materials exchanged during discovery thus far. (See Attached Exhibit A, which comprises Bates No. NECC_MDL000011194.).

The motion at bar currently is a Motion to Quash by TEC. This motion essentially asks the court for protection from responding to notice of deposition by written question on the basis that (1) the information sought by the Premier Defendants is not relevant; (2) TEC did not order MPA, and (3) TEC is unduly burdened by the notice for deposition by written question.

Per the agreed-upon discovery schedule entered by the Premier Defendants to this Court on March 31, 2016, Common-Issue Fact Discovery is currently ongoing until June 1, 2016 with a proposed new deadline of August 1, 2016. (Dkt. No. 2775.)

SUMMARY OF ARGUMENT

The Premier Defendants seek relevant information from TEC regarding their due diligence when deciding to purchase injectable medication from NECC. This information is potentially valuable to buttress expert testimony at trial. TEC is not subject to any undue burden given the targeted nature of the Premier Defendant’s direct-examination questions; further, the deposition by written question format has borne out the Premier Defendants’ anticipations in terms of minimal time and effort required of 30(b)(6) deponents responding for other entities.

ARGUMENT

Discovery is wide-ranging in scope, extending to “any non-privileged matter that is relevant to any party’s claim or defense and proportional to the needs of the case,” regardless of whether the information is admissible in evidence. Fed. R. Civ. Pro. 26(b)(1).

“A Rule 45 subpoena must fall within the scope of proper discovery under [Rule] 26(b)(1).” *Enargy Power (Shenzen) Co. Ltd. v. Xialong Wang*, No. 13-11348-DJC, 2014 WL 2048416 at *2 (D. Mass. May 16, 2014). Therefore, following the 2015 Amendments to Rule 26, “information sought must be: (1) not privileged; [and] (2) relevant to the claim or defense of any party.” *Id.* Additionally, a court is only required to quash a subpoena if the subpoena, among other unrelated factors, “subjects a[n entity] to undue burden.” Fed. R. Civ. Pro. 45(d)(3)(A)(iv).

The 1st Circuit requires the party issuing the subpoena to demonstrate sufficient “factual support” for its contention that the information sought is relevant to that party’s defenses. *Enargy*, 2014 WL 2048416 at *3. Where the party issuing the subpoena speculates as to the “possibility” of relevance without factual support, concedes that it does not need the information, or makes overbroad requests for information, the Court has quashed subpoenas or limited their scope. However, none of those situations apply to the Premier Defendants, who have argued the necessity for this information from the outset, kept their requests for information as targeted and minimal as possible, and will herein provide factual support based on the current record as to the relevance of the information sought. Accordingly, Premier’s subpoena issued to TEC should be upheld.

I. The Premier Defendants Seek Relevant Information Regarding TEC’s Due Diligence in Deciding to Purchase from NECC

The Premier Defendants argued before this Court as to “what other clinics who purchased from NECC did” prior to deciding to purchase from NECC. (Transcript of December 17, 2015 Oral

Argument before Judge Boal, pg. 14 ln. 3-4.) That due diligence was and remains the focus of the Premier Defendants' questions and intent in subpoenaing TEC for a deposition by written question.

a. The Premier Defendants Considered Multiple Factors When Selecting Entities for Deposition by Written Question

When initially deciding to attempt depositions by written question of non-parties, the Premier Defendants determined to notice only ten entities, in keeping with the limits of Rule 31(a)(2)(A)(i) and as a reasonable amount of entities to survey. The Premier Defendants then assessed several other factors when determining which entities to subpoena, cognizant not only of the Premier Defendants' own circumstances but also that common-issue fact discovery was – and is – still ongoing. These factors included, in no particular order: geographic relevance to the Premier Defendants or other defendants, type of medication purchased, number of orders, amount of medication purchased, and size of the ordering entity.

The Premier Defendants selected Central Jersey Orthopedic Specialists, Ross Center for Orthopedics, Montclair Orthopedic Group, and New Jersey Spine and Sports Medicine as the most appropriate of other entities in New Jersey who had purchased MPA from NECC, based in part on the number of doctors at these entities and information available online.

The depositions by written question of larger entities are of great interest to Premier for several relevant reasons. The Premier Defendants relied in part on the due diligence conducted by Settling Defendant Inspira – a moderately sized hospital – when deciding to purchase MPA from NECC. This was in part because of the prior experience of Premier physicians in using NECC's MPA while practicing at Inspira. Additionally, Inspira, as a more sizeable institution than Premier, accordingly had more funds and personnel than Premier. The Premier Defendants inferred that such a larger institution would have more resources to put forth into due diligence above and beyond what the standard of care required. Thus, if as the PSC alleges an in-person inspection of

NECC should have taken place, larger institutions such as TEC and Vanderbilt would have had the resources to do so. Additionally, if as the PSC alleges the standard of care required minimal due diligence, large institutions serving thousands of patients could hardly escape compliance and thus would be more likely to have relevant information.

b. NECC's Marketing Strategy Focused on Persuading Customers to Outsource Entirely To NECC Following Initial Sale

While the choice of product purchased by customers from NECC is relevant (in that those who did not unknowingly purchase tainted MPA are not involved in this litigation), it cannot at this time comprise the sole determinative factor as to whether seeking information on the due diligence behind an entity's decision to purchase from NECC is relevant to the Premier Defendants defenses in this case.

Recent review of NECC's production suggest that NECC's marketing strategy was based on an opening sale subsequently leading to the customer outsourcing more and more to NECC. MSM training videos/audio files record Mr. Cadden stating an intent to build long-term relationships with entities, and indicating that sales reps should be constantly inquiring about product needs for NECC to take over from either the customer or competing compounding entities, such that NECC could become "one-stop shopping" for its customers' various needs. There are several examples in the NECC production of customers who had previously ordered in small quantities, or purchased only a few products from NECC, requesting quotes for products outside their regular orders and demonstrating a desire to expand their purchasing to different products and/or larger amounts without attempting any new or different due diligence into the company. (See Attached Exhibit B.)

The Premier Defendants take the position that it is unlikely a customers would later go back and conduct a new or different investigation into NECC when deciding to expand their

purchasing with NECC in terms of quantity or medication type. At least one of the depositions by written question conducted so far indicates that in some situations, all NECC needed to do was gain a third party buying group's approval as a vendor, following which entities represented by the buying group would contract with NECC for unspecified services without performing any due diligence outside that done by the group. (See Attached Exhibit C: Transcript of March 9, 2016 Deposition by Written Questions of James D. Cathey, 30(b)(6) Witness for East Tennessee Children's Hospital, pg. 7 ln. 18 – pg. 10 ln. 25.) It does not appear from the evidence available thus far that different due diligence was conducted for different products; but rather that once a decision was made to order medications from NECC, regardless of the type of medication being ordered, the same due diligence (if any) was used as the basis to continue ordering from the company. Therefore, regardless of the "type" of drug being ordered, the investigation (if any) of the ordering facility is the useful and relevant information being sought here.

c. TEC Purchased Sterile Injectable Steroid Medication from NECC

It is difficult to predict what the PSC will ultimately allege as a deviation from the standard of care. If the plaintiffs allege that ordering from NECC was negligence without first performing some due diligence, then the ordering practices and any investigation by TEC is relevant. If the PSC alleges that Premier deviated from the standard of care because they did not perform a proper investigation before ordering *sterile injectable medications*, the ordering practices and any investigation performed by TEC is still relevant because TEC purchased Triamcinolone Acetonide from NECC. Triamcinolone Acetonide is the generic of name-brand medication Kenalog – an injectable steroid and other sterile compounded drugs. NECC's version is marketed as "Preservative-Free Kenalog." There is no practical difference between sterile injectable medications for the purposes of this discovery request and motion: all injectable medications must

be sterile and free of contaminants when introduced into the human body. The standard of care applicable to TEC when deciding to purchase injectable steroid medication from NECC was identical to that which applied to the Premier Defendants when deciding to purchase MPA from NECC.

Accordingly, TEC does not have a basis for claiming that any “information sought is irrelevant.” (TEC Motion to Quash Subpoena, Dkt. No. 2788, pg. 1.) Emory purchased preservative-free injectable steroid, which also should have been sterile and subject to the same due diligence as the standard of care required for purchase of MPA.

II. The Premier Defendants Intend To Offer Evidence Of The Standard Of Care With Information Gained Via Depositions by Written Question

Whether other institutions actually performed the investigations the PSC contends were required is information which can be used in support of expert testimony at trial. The Premier Defendants are cognizant of the applicable New Jersey law and do not suggest that such information would be used in place of expert testimony to establish the standard of care.

However, information obtained from TEC can be used to bolster expert testimony and is potentially useful in assisting the jury in determining the standard of care in the community. Obtaining information from entities both analogous to and surpassing the Premier Defendants in size and resources is useful to support the Premier Defendants’ position that in 2012, the standard of care did not require the extensive checks the PSC contends were required. TEC’s argument regarding its testimony and samples sizes is an insufficient basis to deprive the Premier Defendants of the opportunity to ask questions at this stage.

It may be the case that TEC investigated NECC during the relevant time period and found the facility to be reputable and suitable for their purposes of ordering compounded medications. Such evidence would be extremely relevant to prove just exactly what would have been found if Premier

performed the same investigation at that same time – in other words the information is potentially relevant to causation, not only standard of care.

III. The Premier Defendants’ Direct-Examination Questions Do Not Subject TEC to “Undue Burden”

Premier Defendant’s goal as demonstrated by the specific wording of the questions asked is to gather targeted information as to the due diligence conducted by these institutions. Premier Defendants ask only 21 questions and, as explained to the Court previously, undertook to keep the burden imposed on non-parties as minimal as possible via not only deposition format but also number of questions and topics addressed by the subpoena. (Dkt. No. 2385.) It is difficult to imagine how the Premier Defendants’ questions could have been more limited while still conforming with litigation practice rules and ascertaining the information necessary. The Court already ruled on similar issues asserted by the PSC in their motion to convert the depositions by written question to oral format, and found in favor of the Premier Defendants. (Dkt. No. 2528.)

The Premier Defendants do not answer for the cross-examination questions posed by the PSC and lodged multiple objections to form with the Court within the appropriate time period regarding the PSC’s cross-examination. (Dkt. No. 2640.)

Thus far, depositions by written question of the following entities noticed by the Premier Defendants have occurred without issue: Ross Center for Orthopedics, Montclair Orthopedic Group, Central Jersey Orthopedic Specialists, and University of Tennessee Medical Center. The Premier Defendants have been working towards scheduling the deposition of New Jersey Spine & Sports Medicine throughout, and anticipate that deposition will take place without issue before the current close of common fact discovery. Even so, the sum total without TEC and Vanderbilt would result in only five of the original ten depositions for which the Premier Defendants attempted

notice. Multiple depositions by written question noticed by the Box Hill Defendants have taken place at this point, also without issue.

As a whole, these depositions appear to take around two hours or less, and the majority of that time is used reading and responding to cross-examination questions posed by the PSC. Generally it appears that the Premier Defendants' initial anticipations of the minimal burden imposed on non-party deponents, as well as the expected answers to questions, have been borne out in the depositions which have taken place.

a. TEC's 30(b)(6) Deponent Must Testify as to "Information Known or Reasonably Available"

Under Rule 30(b)(6), an organization noticed to produce a corporate representative as its deponent is required only to produce an individual who "consent[s] to testify on [the organization's] behalf about information known or reasonably available to the organization." Fed. R. Civ. Pro. 30(b)(6). TEC claims that as the individual "responsible for purchasing medications from NECC[] died in 2012," TEC is "incapable of producing a witness with first-hand knowledge of most of the information sought." (TEC Motion to Quash Subpoena, Dkt. No. 2788, pg. 12). However, while producing an individual with first-hand knowledge is ideal, it is by no means required by the Federal Rules. Ultimately, TEC is only required to produce a deponent — who may be an individual educated to the knowledge sought — to testify to information "reasonably available" to TEC.

Further, in an entity as large as TEC self-describes, it is highly unlikely that one person was solely responsible for the decision to purchase from NECC. Notably, while TEC indicates that the individual who ordered from NECC is unavailable, TEC makes no mention about the individuals involved in the decision to purchase from NECC — those from whom the Premier Defendants are actually interested in obtaining information.

b. No Reasonable Reading of Rule 30(b)(6) Requires the “Significant Efforts” TEC Claims

TEC has already identified the individual previously responsible for ordering from NECC, and from there it is unlikely to require extensive effort to determine what information her supervisor or replacement hold. TEC certainly must have readily available current knowledge as to its due diligence in choosing vendors, and going back less than four years to determine the state of knowledge in May 2012 is not an insurmountable time frame to traverse.

CONCLUSION

For the reasons stated herein, the Premier Defendants respectfully request that the Court DENY The Emory Clinic’s Motion to Quash the Premier Defendants’ Subpoena for Deposition by Written Question.

Dated: April 21, 2016

Respectfully submitted,

Blumberg & Wolk, LLC
158 Delaware Street
P.O. Box 68
Woodbury New Jersey 08096
(856) 848-7472
cwolk@blumberglawoffices.com

/s/ Christopher M. Wolk
Christopher M. Wolk, Esq.

*Attorneys for Premier Orthopaedic and Sports
Medicine Associates of Southern New Jersey, LLC,
trading as Premier Orthopaedic Associates, Premier
Orthopaedic Associates Surgical Center, LLC,
Kimberly Yvette Smith, M.D., a/k/a Kimberly Yvette
Smith-Martin, M.D., Thomas Dwyer, M.D., Richard
C. DiVerniero, M.D., and Richard Strauss, M.D.*

CERTIFICATION

I certify that in submitting this *OPPOSITION*, I caused a copy of the above to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's System, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Dated: April 21, 2016

/s/ Christopher M. Wolk
Christopher M. Wolk, Esq.